

Remarks

Claims 1, 3-8, 10-21, and 23-40 are pending in this application. Claims 1, 17, 21, and 32 have been amended, and no claims have been added or canceled. Reconsideration of this application is respectfully requested in light of the above amendments and the following remarks.

Rejection of Claim 1 and its dependent claims Under 35 U.S.C. §112, ¶1

Claims 1, 3-8, and 10-16 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the previous amendment of “. . . without disposing the cells within an exogenous scaffold material. . .” introduced new matter which is not described in the specification. In response, Applicants note that the Background Art section of the specification discusses prior art cultures which are “grown within synthetic matrices” or “within a chitosan scaffold material” (see p. 1, lines 18-21; p. 2, lines 5-8), and that a self-organizing construct is thus one that is formed without disposing cells within an exogenous scaffold. However, in order to expedite prosecution of this case, Applicants have amended independent claims 1, 17, and 32 to clarify that cardiac cells are “provided on the substrate without an exogenous scaffold material” as clearly supported in the specification (for example, p. 3, lines 1-8; p. 6, lines 6-11) and in direct contrast to the previously cited art. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of Claim 1 and its dependent claims Under 35 U.S.C. §112, ¶2

Claims 1, 3-8, and 10-16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite due to the statement “. . . and subsequently permit the monolayer to detach.” Applicants have clarified the claim language of claims 1, 17, and 32 to recite “the substrate configured to permit the monolayer to detach from the substrate and self-organize to form a three-dimensional cardiac muscle construct,” such that the claims now recite a limitation of the substrate and not the monolayer.

With regard to the rejection of claim 21, Applicants appreciate the Examiner's careful review of the application and have amended this claim herein to recite the "method". Accordingly, reconsideration and withdrawal of these rejections is also respectfully requested.

Rejection of Claims 9-11 and 22-24 Under 35 U.S.C. §112, ¶ 2

The Examiner has maintained the rejection of claims 9-11 and 22-24 under 35 U.S.C. §112, second paragraph, asserting that the function of the "anchors" in claims 9 and 10 is unclear. As Applicants canceled claims 9 and 22 in response to the previous Office Action, Applicants will address this rejection with respect to independent claims 1, 17, and 32 which each recite "at least two anchors secured to the substrate in spaced relationship."

The Examiner states that "the anchors may actually be serving as a scaffold-like structure" (Office Action, p. 3). In response, Applicants have amended independent claims 1, 17, and 32 to recite "at least two anchors secured to the substrate in spaced relationship . . .wherein only some of the cells are in contact with the anchors" (emphasis added). Support for this amendment can be found, for example, at p. 8, lines 13-25 and p. 9, lines 1-3 of the specification, and clearly shown in FIGS. 1A-1D. Therefore, some of the cells are in contact with the spaced-apart anchors which, as is known to those skilled in the art, function as spaced, discrete attachment points for the developing tissue. In contrast, a scaffold is understood by those skilled in the art to be a three-dimensional growth surface into which the totality of the cells are introduced and which serves to at least partially stand in place of naturally generated extracellular matrix materials (see Background Art). In the system and method of the present invention, the anchors do not extend into the contractile region of the self-organizing tissue (*see* p. 6, lines 6-11), as now clarified by the claim language that "only some of the cells are in contact with the anchors", and thus cannot be confused with a prior art scaffold. Furthermore, Applicants' specification is clear on the distinction between anchors and scaffold material, especially since these are terms well known in the art.

The Examiner also states that "the spatial relationship of the anchors appears to be essential for the growth of cells in the invention and should be clearly defined" (*see*

Office Action, pp. 3-4). Applicants submit that claims 1, 17, and 32 do clearly define the spatial relationship of the anchors, in that at least two anchors are spaced apart with only some of the cardiac cells in contact therewith. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Double Patenting

Claims 1, 3-7, 10-21, 23-27, 29, 32-36, and 40 have been rejected under nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, 12-13, 15-19, 21-23, 26, and 28-31 of U.S. Patent No. 6,207,451. Applicants acknowledge this rejection, and reserve the right to file a terminal disclaimer in order to overcome the rejection once the claims are otherwise in allowable condition.

Conclusion

In summary, Applicants believe that the claims meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

The Petition fee, as well as any additional fees or credit of any overpayments as a result of the filing of this paper, is being charged to our Deposit Account No. 02-3978.

Respectfully submitted,

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